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EXAMINER

RADEMACHER, MARK A

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/465,054

Applicant(s)

BURTON, DAVID

Examiner

Mark Rademacher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 32-56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

1. In the Office Action mailed on December 18, 2002, the drawings are objected to under 37 CFR 1.83(a) because they did not show every feature of the invention specified in the claims. In response the applicant deleted these items from the claims. Accordingly the objection to the drawings is withdrawn.

Specification

2. The disclosure was objected to because for informalities. The applicant's corrections are acceptable. The objections raised in the initial Office Action are withdrawn.

Claim Objections

3. The objection to cancelled claim 19 is withdrawn.

4. Claims 32-56 are objected to because of the following inconsistencies in the claims. The preamble of the claims refers to "a mask with sensors". However, the applicant recites "at least one sensor" in the claims. It appears the applicant intends the preamble to read "a mask with at least one sensor".

5. In line 3 of claim 34, the applicant recites "the sensors". It is unclear whether the applicant intends to require a plurality of sensors or simply one or more sensors. It appears that the applicant intends to refer to "the at least one sensor".

6. In claim 38, the applicant recites "one of the at least one sensor". It appears that the applicant intends to refer to "the at least one sensor" and that the wording "one of the" should be deleted.

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7. In at least claims 43 and 45 the applicant utilizes the transition phrase “wherein” when it appears that the transition phrase should be “further comprising”.

8. The applicant is required to make appropriate corrections to the claims including corrections to other claims with like inconsistencies.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 32-56 are rejected under 35 U.S.C. 101 because the claimed invention appears to be directed to non-statutory subject matter. Specifically, in claim 32 the applicant recites “at least one sensor on the perimeter of the mask makes contact with the face of the patient”. That language appears to include within its scope a human being, which is not patentable subject matter since property rights in human beings are prohibited. 1077 OG 24 (April 21, 1987).

11. The applicant includes similar recitations of parts being in contacting or engaging a human being in claims 33, 34, 35, 48, 51 and 52.

12. The applicant can overcome the rejection by amending the language to recite that a component is “adapted to engage” or “adapted to contact” or “is configured for contacting” etc. For example in claim 1, the applicant may amend the relevant clause to “at least one sensor on the perimeter of the mask ‘*is adapted to*’ make contact with the face of the patient”.

Claim Rejections - 35 USC § 112

First Paragraph

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. The rejection of cancelled claims 21 and 23-31 under 35 USC 112, first paragraph for lack of written description is withdrawn.

15. However new claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

16. With respect to claim 39, the applicant has not adequately described a gas flow, airflow sensor, mask pressure sensor, gas pressure sensor patient back gas sensor, light sensor that contacts the face of the wearer.

17. Instead, the applicant specifically states that sensors (26) that measure ambient light, gas pressure, are not in contact with the patient's skin. See, e.g., page 6, lines 6-8 of the applicant's disclosure.

18. The more detailed discussion of flow and pressure sensors describes the sensors being located in zone (70), which is not in the perimeter of the mask. See, e.g., FIG 5.

19. The applicant's disclosure does not adequately describe how such sensors would be configured to sense air pressures and flows if the sensors were in contact with the wearer as required by the claim.

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20. The applicant is invited to point out in the specification support for the above claims.

Generally, the applicant is required to specifically point out the support for any amendments made to the claims and disclosure. MPEP §§ 714.02, 2163.06.

Second Paragraph

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. Claims 38, 41, 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

23. In claim 38, the applicant recites means for providing power to the mask to operate the sensors comprising "a mask interface connector" and later recites that means for transmitting data from the mask comprises "a mask interface connector". The metes and bounds of the claim are not ascertainable to one with ordinary skill because it is unclear from the claim whether the same connector is recited twice, or whether first and second connectors are being recited. If the applicant intends to refer to a single connector, the examiner suggests amending the claim to refer to "the mask interface connector" in the second instance.

24. In claim 41, the applicant recites "the strap has at least one sensor wired to the mask". However, in the parent claim 32, the applicant recites "at least one sensor on the perimeter". The metes and bounds of the claims are unclear because it is unclear to one with ordinary skill whether the applicant is reciting a second sensor on the strap, or somehow placing the same at least one sensor on both the strap and in the perimeter of the mask.

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25. Claims 44 and 45 are similarly indefinite because of the recitation of “at least one sensor attached to the cap” and “at least one sensor in the chin strap” respectively.

26. The applicant is invited to review the claims for like instances of indefiniteness and make appropriate corrections.

Claim Rejections - 35 USC § 102

27. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

28. Claims 32-34, 37, 39, 40, 43 and 49 are rejected under 35 U.S.C. 102(e) as anticipated by US patent no. 6,199,550 to *Wiesmann et al.*

29. *Wiesmann et al* disclose a mask that incorporates physiological sensors. As seen in FIG 1, the mask includes straps, a hose connector (not numbered) for connecting a source of air (12) through the breathing tube (13). The mask includes at least one sensor (e.g., photoelectric sensor (130)) that is located in a recess in a sealing rim (50) located at the perimeter on the mask's outer edge. The sensor is configured in the sealing rim to make contact with the wearer when the mask is worn. See, e.g., FIG 3 and column 5, lines 22-36. *Wiesmann et al* disclose that a number of sensors may be employed in the mask at least including heart rate – pulse oximeter sensor and temperature.

30. The sensor is connected via leads (e.g., wires 111, 121, 131 connected to the photoelectric sensor) to a means for transmitting data from the mask in the form of a connector

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(152), processor (160) and a transmitter (14). The lead wires are located in the outer edge perimeter of the mask.

31. With respect to claim 34, although *Wiesmann et al* is silent as to the material with which the sealing rim (50) is formed, it is the examiner's position that the sealing rim must be formed of a soft pliable material such as that disclosed by the applicant since the sealing rim (50) functions to seal the perimeter of the mask to the face of the wearer and therefore must be soft and pliable to the extent necessary to allow the mask a seal the perimeter of the mask against the wearer.

32. With respect to the cap recited in claim 43, *Wiesmann et al* show that the mask can include a cap in the form of a helmet shown in FIG 1, which together with the straps holds the mask in place.

33. With respect to claim 49, *Wiesmann et al* disclose a thermal sensor in the form of contact thermometer (70).

Claim Rejections - 35 USC § 102/§ 103

34. Claim 36 and 38 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US patent no. 6,199,550 to *Wiesmann et al*.

35. According to *Wiesmann et al*, the lead wires lead to an interface connector (152) that connects the leads to the processor (160), which is hard-wired to the transmitter (14). See, e.g., column 6, lines 47-51 and column 13, lines 55-63.

36. *Wiesmann et al* further disclose that means for providing power to the mask to operate the sensors that includes a power source for transmitting power to the sensors and the transmitter.

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See, e.g., column 13, lines 59-61. The power source is contained in the transmitter, which is wired to the sensors through the connector (152).

37. If, however, the applicant successfully asserts that a cable is somehow distinguishable from the wiring disclosed by *Wiesmann et al*, it is the examiner's position that the use of a cable to connect leads from sensors to a transmitter, power source, or the like is well known in the art. See, e.g., column 5, lines 34-37 of US invention registration no. H1039 to *Tripp, Jr., et al*. At the time of invention it would have been an obvious modification to alter the wiring disclosed by *Wiesmann et al* to include a cable to connected to the connector in order to consolidate and protect the sensor wiring.

Claim Rejections - 35 USC § 103

38. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

39. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. *Wiesmann et al* in view of US patent no. 3,606,881 to *Woodson*.

40. *Weismann et al* disclose all of the features of claim 36 without expressly disclosing a carbon embedded rubber material that provides electrical contact between the sensor in the soft pliable material the

41. Carbon-embedded rubber materials used for electrical contact between a person's skin and a sensing means are well known in the art. For example, the disclosure of *Woodson* teaches a conductive rubber electrode 16 that is composed of an electrically conductive silicon rubber

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material filled with an electrically conductive substance such as carbon, graphite or silver. See column 2, lines 24-29.

42. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use a conductive rubber electrode in the mask disclosed by *Wisemann et al* to achieve the device recited in claim 35 in order to create reliable electrical contact between the skin of the wearer and the sensor with out the use of irritating gels or the like. See, e.g., *Woodson*, column 1, lines 32-42.

Claims 41, 43 and 44

43. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 6,199,550 to *Wiesmann et al* in view of the teaching in the disclosure in US patent no. 5,503,147 to *Bertheau*.

44. *Wiesmann et al* disclose all of the features recited in claims 41, 43 and 44 without expressly disclosing that one of the straps includes a sensor wired to the mask, or that a cap includes a sensor.

45. *Bertheau* discloses a respiratory mask having straps 16 that include a sensor (84) located on the harness (16). See FIG 10 for example.

46. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the mask disclosed by *Wiesmann et al* to include straps having sensors wired therein as taught by *Bertheau*. Regarding claim 44, that portion of the harness (16) that fits over the head of the wearer rather than the neck or the chin comprises a cap, which also includes a sensor (84). See, e.g., FIG 1. *Bertheau* also discloses that the cap includes a sensor (84) attached thereto and delivers an output signal to a control component.

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47. At the time the invention was made, it would have been obvious of a person of ordinary skill in the art to modify the mask by *Wiesmann et al* to create the mask recited in claims 41, 43 and 44 in order to better secure and monitor the fit of the mask to the wearer. See *Bertheau* column 6, lines 54-66 for example.

Claims 42 and 45-47

48. Claims 42 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Wiesmann et al* in view of the *Bertheau* as applied to claim 41 above, and further in view of the teaching in US patent no. 6,032,065 to *Brown*.

49. *Wiesmann et al* in view of *Bertheau* teach a mask including all of the features of the mask recited in claim 41 without expressly teaching a mask having a chin strap including a sensor, as recited in claim 42, a chinstrap including a sensor for “measuring chin EMG”, as recited in claim 45, a head strap having a sensor “for measuring EEG”, as recited in claim 46, or a cap that includes a sensor “for measuring EEG” as recited in claim 47.

50. *Brown* teaches a sensor mask that includes EMG sensors and EEG sensors located in the mouth/chin portion of the mask and the head portion of the mask. See FIG 2 for example and the accompanying discussion in column 3, lines 30-47. As seen in FIG 2, the EMG sensor is located in the chinstrap and the EEG sensors are located in a head strap, which may also be considered a cap.

51. At the time of invention, it would have been obvious to one with ordinary skill in the art to modify the mask taught by *Wiesmann et al* and *Bertheau* to include the EEG and EMG sensors located in straps on the head and chin of the wearer as taught by *Brown* in order to increase the physiological data collected from the wearer of the mask.

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52. Claim 48

53. Claim 48 rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 6,199,550 to *Wiesmann et al* in view of US patent no. 5503147 to *Bertheau* as applied to claim 41 above, and further in view of US patent no. 5,673,692 to *Schulze et al*.

54. The disclosure of *Wiesmann et al* in view of *Bertheau* does not expressly teach an ear strap having an oxygen saturation sensor applied to the ear of the patient.

55. *Schulze et al* disclose an oximeter (70) that is applied to the ear of a patient and which may be incorporated into a larger structure such as an earmuff 76. See FIGS 1 and 4 and the accompanying discussion in column 5, lines 51-56.

56. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add a blood oxygen sensor applied to the ear in an ear strap to the mask taught by *Wiesmann et al* and *Bertheau* in order to space the oximeter sensor apart from other sensors in the mask thereby preventing the potential of interference between the sensors, and because it is well known that the ear is an acceptable area on the head of a person to measure blood oxygen levels.

Claims 49-54

57. Claims 49-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosure in US patent no. 6,199,550 to *Wisemann et al* in view of the teaching in US patent no. 5,134,995 to *Gruenke et al*.

58. *Wisemann et al* disclose all of the features in the claims without expressly disclosing a thermal sensor on a portion of the mask that detects changes in temperature on that portion of the mask.

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59. *Gruenke et al* disclose the use of thermal sensors, specifically thermistors or thermocouples located proximate the nose or mouth of a patient to detect physiological changes in the patient. See, e.g., *Gruenke et al* column 23 lines 56-61.

60. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the use of thermal sensors with the mask disclosed by *Wisemann et al* in order to monitor the breathing functions of the wearer of a mask for example. See, e.g., *Gruenke et al* column 23 lines 56-61.

61. With respect to the location of the sensors, their locations, i.e., internal or external of the mask, *Wisemann et al* disclose sensors on both the external surface (e.g., temperature sensor 26) and the internal surface of the mask (e.g., carbon monoxide sensor 30).

Claims 50 and 56

62. Claims 50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent no. 6,199,550 to *Wisemann et al* in view of the teaching in US patent no. 5,134,995 to *Gruenke et al* in claim 49 above, and further in view of US patent no. 6,357,440 to *Hansen et al*.

63. Although the *Wisemann et al* and *Gruenke et al* do not expressly teach that the thermally resistive material comprises a coating on the mask, *Hansen et al* teaches such a coating in the context of a pliable respiratory mask. Specifically, coating (115) is a plastic material. Plastic materials are inherently thermally sensitive, i.e., have physical characteristics that change in response to temperature changes. For example, the malleability of many plastics increases as the temperature increases.

64. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add a thermally sensitive coating as taught by *Hansen et al* to the mask taught

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by *Wisemann et al* and *Gruenke et al* in order to decrease the bulkiness of the mask and create a continuous surface of "thermally sensitive" material on the mask.

Additional Pertinent Prior Art

US patent no. 5,617,849 to *Springett et al* and US patent no. 6,240,921 to *Brydon* are considered pertinent to the applicant's disclosure.

Response to Arguments


65. Applicant's arguments with respect to new claims have been considered but are moot in view of the new ground(s) of rejection.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR 
June 11, 2003


GLENN K. DAWSON
PRIMARY EXAMINER